



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,425

12/27/2006

Jorg Feesche

H06291 (13744-00021)

5960

23416

7590

09/11/2009

CONNOLLY BOVE LODGE & HUTZ, LLP

P O BOX 2207

WILMINGTON, DE 19899

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

09/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/593,425	FEESCHE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8/5/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11,13,14,16-21,23-34 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5-11,13,14,16,20,21,23,25-34 and 48-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-19 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2006:8/2008</u>   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1645

**DETAILED ACTION**

Claims 1-2, 5-11, 13-14, 16-21, 23-34, 48-54 are pending.

***Lack of Unity of Invention***

1. Applicant's election with traverse of Group IV, species I, directed to gram negative bacterium that is not *Bacillus megaterium* in which the gene *recA* is functionally inactivated, in the reply filed on August 5, 2009 is acknowledged. The traversal is on the ground(s) that there is Unity of Invention, and a Lack of Unity does not exist as the claimed inventions are linked by a special technical feature that makes a contribution over the prior art.

2. Applicant asserts (Remarks submitted May 14, 2009 and August 5, 2009) that there is Unity of Invention because US PG-Pub 2008/005077 did not know or appreciate at the time of the provisional application, that the hypothetical ORF of SEQ Id NO 1819 in the provisional application encoded a RecA protein and designated the coding sequence to be Yxid, which is otherwise known as Transposase 30.

3. It is the position of the examiner that SEQ ID NO 1819 of US PG-Pub 2008/0050774 was originally designated SEQ ID NO 1358 in Provisional application 60/535988 and was described as encoding RecA (see below). SEQ ID NO 1358 of the provisional application is identical to PG-Pub 2008/0050774 SEQ ID NO 1819. SEQ ID NO 1358 encodes RecA protein SEQ ID NO 5502 (provisional application designator) which is later known as SEQ ID NO 6016 in the PG-Pub 2008/005077; SEQ ID NO 1358 encodes RecA .

Table 1. Predicted function

SEQ ID NO	Predicted function (similarity to other genes)	Nearest <i>B subtilis</i> orthologue	COG classification
1358	NF01158416: RecA protein [ <i>Bacillus amyloquelaciens</i> ]; similar to BG10721 - multifunctional protein	RecA	L3

Art Unit: 1645

4. Therefore coding sequence for RecA SEQ ID No 1358 (later known as SEQ ID NO 1819) was disclosed in the earliest filed provisional application which encodes RecA protein (SEQ ID NO 5502, later known as SEQ ID NO 6016). Lack of Unity still exists, as the first appearing invention is described and disclosed in US PG-Pub 2008/0050774 which has priority back to January 9, 2004. The RecA protein of 2008/0050774 shares 99.5 % sequence identity with SEQ ID NO 2 which is encompassed by the claimed genus of RecA factors with 96% identity to SEQ ID NO 2. US PG-Pub 2008/0050774 still anticipates and describes the first appearing invention. Claims 17-19 and 24 are under consideration

5. Claims 1-2, 5-11, 13-14, 16, 20-21, 23, 25-34, 48-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups I, II, III, V-IX, and non-elected species in Group IV there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on August 5, 2009.

&lt;210&gt; 1358

&lt;211&gt; 1047

&lt;212&gt; DNA

<213> *Bacillus licheniformis*

&lt;400&gt; 1358

```

atgagtgtac gtcaggcagc cttagatatg gcgcttaaac aaatagaaaa gcagtttggt    60
aaagggttcga ttatgaaact cggcgaacaa actgaaacga gaatttcaac agttccgagc    120
ggttcttttag cgctcgatgc ggctcttggg gtggcgcgat acccgcgcgg ccggattatt    180
gaagtatacg ggcctgaaag ctccggtaaa acgacgggtg cgcttcatgc gattgccgaa    240
gttcagcagc agggcggaca agcggcggtc atcgacgccc aacacgcgct tgatcccgtc    300
tatgcacaaa agctgggctg caacattgat gagcttttgc tgtcacagcc tgatacgggc    360
gagcaggcgc tcgaaatcgc tgaagccctt gtcagaagcg gagcgggtga tatcgttggc    420
atcgactctg tagcagcgtg tgtgccgaaa gctgaaatcg aaggagatat gggggattcc    480
cacgtcgggt tgcaggccag actgatgtct caggcgcttc gcaagcttcc cggagcgtac    540
aataaatcga agaccatcgc gatctttatc aaccagattc gtgaaaaagt cgggtgtcatg    600
tttgaaatc ctgagacgac gccaggcggg agagcgctga aattctactc ttctgtccgc    660
cttgaagtgc gcccgcgaga gcagctgaaa caaggcaacg acgtcatggg gaacaagacg    720
aaaatcaaa tcgtgaaaaa caaagtggca cctccattcc ggacagccga agtgacatt    780
atgtacgggg aagggaattc aaaagaaggg gaaatcatcg acctcggaac agagcttgac    840
atcgttcaaa agagcgggtg atggtactct tatcaggagg aacgccttgg acaaggccgt    900
gaaaacgcca aacagtctct gaaagaaaac aagatatccc tttgatgat tcaagagcag    960

```

Art Unit: 1645

atccgggagc actacgggtt ggatactgga ggcgctgctc ctgcacagga agacgaggcc 1020  
caagctcagg aagaactga gttttaa 1047

Provisional Application 593,425 sequence 5502 is identical to SEQ ID NO 6016 of US Application number 10/593,425.

Provisional Application 593,425 sequence 5502 is identical to SEQ ID NO 6016 of US Application number 10/593,425.

### ***Information Disclosure Statement***

6. The information disclosure statement filed September 19, 2006 and August 12, 2008 have been considered.

### ***Priority***

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Sequence Compliance and Specification Hyperlinks***

8. The instant Application is now in sequence compliance.

9. Applicant's amendment of the Specification removing embedded hyperlinks obviates the previous objection to the Specification.

Art Unit: 1645

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 17-19 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US PG-Pub 2008/0050774, with priority to January 9, 2004 in US Provisional Application 60/535,988 .

12. Pub 2008/0050774 discloses the instantly claimed invention directed to:

13. A mutant gram positive bacterium, *Bacillus licheniformis*, with a disrupted or deleted gene of SEQ ID NO 1819 (see PG-Pub original claims 36-38 and original claim 17; provisional application original claims 19 and 38-39), the mutant gram positive bacterium having less RecA biologically active substance than in the parent cell. The mutation being in the coding sequence of SEQ ID NO 1819 resulting in a mutant having the recA gene deleted or disrupted (claim 35 depending from claim 17 in PG-Pub; which were claimed as claim 19 and 38 of the Provisional application for SEQ Id NO 1358, RecA)

Table 1. Predicted function

SEQ ID NO	Predicted function (similarity to other genes)	Nearest <i>B subtilis</i> orthologue	COG classification
1358	NF01168416: RecA protein [ <i>Bacillus amyloliquefaciens</i> ]; similar to BG10721 - multifunctional protein	RecA	1.3

The mutant gram positive bacterium with a disrupted recA gene had a coding sequence prior to mutation that shares 99.5% sequence identity at the genetic level with the instantly claimed coding sequence SEQ ID No 1.

```
Sequence 1019, Application US/10900120
Publication No. US20080050774A1
GENERAL INFORMATION:
APPLICANT: BEDIA, Randy
APPLICANT: BRY, Michael
APPLICANT: KAMALIYA, Preeti
APPLICANT: ANDERSEN, Jens Torne
APPLICANT: RASMUSSEN, Michael Bullelu
APPLICANT: OLSEN, Peter Dicks
TITLE OF INVENTION: Bacillus licheniformis Chromosome
FILE REFERENCE: 10589, 300 US
CURRENT APPLICATION NUMBER: US/10/993,128
PRIOR APPLICATION NUMBER: 01/2505,498
FILING DATE: 2004-01-09
PRIOR APPLICATION NUMBER: 80/381,053
FILING DATE: 2004-04-03
PRIOR APPLICATION NUMBER: 00/072,403
FILING DATE: 2003-05-10
NUMBER OF SEQ ID NOS: 335
SOFTWARE: FASTSEQ FOR Windows Version 4.0
SEQ ID NO: 113
LENGTH: 1047
TYPE: DNA
ORGANISM: Bacillus licheniformis
US-10-900-120-1019
Query Match 99.5% Seqs 1042.3/ DB 17; Length 1047;
Eseq Local Similarity 95.7% Freq: No. 0/
Matches 1042: Conservative 0/ Mismatches 3/ Indels 0/ Gaps 0/
QY 1 ATGAGTCATCCTCAGCCAGCCTTAGATATGCGCCTTAAACAAATAGAAAAAGCAGTTTGGT 50
DL 1 ATGAGTCATCCTCAGCCAGCCTTAGATATGCGCCTTAAACAAATAGAAAAAGCAGTTTGGT 50
QY 61 AAAGCTTCCATTATCAAACTCCGCCCAACAACTCAAAACGACAATTTCAACACTTCCCGACC 120
DL 61 AAAGCTTCCATTATCAAACTCCGCCCAACAACTCAAAACGACAATTTCAACACTTCCCGACC 120
QY 121 GCTTCCTTAGCCTTCGATTCGCTCTTCGATTCGCTTCGATTCGCTTCGATTCGCTTCGATTC 180
DL 121 GCTTCCTTAGCCTTCGATTCGCTCTTCGATTCGCTTCGATTCGCTTCGATTCGCTTCGATTC 180
QY 181 CAAGTATACCCGCCCTCAAAAGCTCCCGTAAACACCGCTCCCGCTTCATCCCGATTCCCGCAA 240
DL 181 CAAGTATACCCGCCCTCAAAAGCTCCCGTAAACACCGCTCCCGCTTCATCCCGATTCCCGCAA 240
```

Pub 2008/005077 anticipates the instantly claimed invention as now claimed.

14. Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Colston et al (WO02/50262, publication date 2002).

Colston et al disclose the instantly claimed invention directed to a gram positive bacterium, *Mycobacterium tuberculosis* or *M. bovis* GCG, in which the gene recA is functionally inactivated, wherein the inactivation is by mutation within the recA coding sequence (see abstract, page 6, paragraphs 4-6; pg 7, p. 1 “inactivation of the recA gene”... “insertion, deletion or frame shift mutation”)

Colston et al anticipates the instantly claimed invention as now claimed.

Art Unit: 1645

15. Claims 17 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubensky, JR et al (US PG-Pub 2004/0197343, filing date February 6, 2004).

Dubensky, JR et al disclose the instantly claimed invention directed to a gram positive bacterium, *Mycobacterium tuberculosis* (claims 11-13) or *Bacillus anthracis* (claims 11, 12, 14) or *Listeria monocytogenes* (claims 11,12 and 15), in which the gene *recA* is functionally inactivated (see claim 11), wherein the inactivation is by mutation within the *recA* coding sequence ( see claims 9 and 11)

Dubensky, JR et al anticipates the instantly claimed invention as now claimed.

16. Claims 17 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuyts et al (2001).

Nuyts et al disclose a mutant *Clostridium* strain, the mutant having a mutation in the *recA* gene promoter (see Figure 1, “*recA* deleted Cheo box”) which resulted in no activation of *recA* following irradiation “no difference was seen between irradiated and non-irradiated samples”, (see page 467, col. 1, lines 4-6), thus showing inactivation of the *recA* gene by deletion of the Cheo box in the *recA* promoter. Nuyts et al anticipates the instantly claimed invention in light of the fact that a gene is the combination of all regulator sequences together with the coding sequence for a gene product, Nuyts et al disclosing a mutation in the gene promoter to inactivate *recA*.



Art Unit: 1645

***Conclusion***

This is a non-final action.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references are being cited to show recA mutant strains of bacteria.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.

The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/  
Examiner, Art Unit 1645  
September 8, 2009

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645